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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/177,427	10/22/98	LUKAS S	4804-4

HM22/0526

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EXAMINER	
BERMAN, A	
ART UNIT	**PAPER NUMBER**
1615	9

DATE MAILED: 05/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/177,427	Lukas et al.
Examiner	**Group Art Unit**
Alysia Berman	1615

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 2 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-9 and 11* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-9 and 11* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Receipt is acknowledged of Preliminary Amendment A filed on 22 October 1998, Response to Notice of Missing Parts and Declaration filed on 15 January 1999 and the Information Disclosure Statement filed 19 February 1999. The International Search Report has been considered.

Per a telephone conversation with John Tutungian, the earlier Office Action, paper no. 5, dated 25 February 1999 has been withdrawn so that the Information Disclosure Statement may be considered. The time to respond will be set to expire 2 months after the date of the second Office Action.

Specification

A substitute specification including the claims is required pursuant to 37 CFR 1.125(a) because there is a vertical line running down the middle of each page. For purposes of clarity a substitute specification is required.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the

amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> > (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Blank et al. (US 4767789). Blank teaches a formulation for spray dried acetaminophen powder coated with ethyl cellulose (title and abstract). The composition was produced by mixing the ethyl cellulose and acetaminophen in methylene chloride and then spray drying the mixture (example 1, column 2). Without evidence to the contrary, the particle size of the core and the coating amount and thickness are not considered critical to the invention.

Claims 1-8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sparks et al. (AC). Sparks discloses controlled release taste-masked particles comprising either antibiotics such as erythromycin or analgesics such as acetaminophen coated with a polymer such as ethyl cellulose. The drug is mixed with the polymer and spray dried (col.6, lines 29-32). The particle size of the powder is from 5 to 100 microns (col. 5, lines 63-64) and the drug is possibly less than 10 microns (col. 6, lines 15-17). The reference appears to read on the amount of polymer coating in column 6, lines 21-22. Without evidence to the contrary, the thickness of the coating is not considered critical to the invention. Since the reference is silent as to the thickness of the coating

but achieves the desired results of applicant of controlled release and taste-masking, the thickness of the coating is not given patentable weight.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Lu et al. (US 4808411). Lu discloses dried particle compositions containing clarithromycin and optionally coated with ethyl cellulose (col. 4, lines 37-39 and 57-61).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blank in view of Morella et al. (US 5378474). Blank teaches all the limitations of the claims as stated above. Blank does not teach the particle size of the core or the amount of coating present in the total formulation. Morella teaches a pharmaceutical composition with a core containing a pharmaceutically active substance coated with a hybrid coating which may contain ethyl cellulose (claim 1). Formulation 1 in column 13 teaches that the coating comprises about 18% of the total formulation by weight. The coating thickness can be between 5 and 200 microns. However, the thickness may be varied to obtain the desired release rate (col. 8, line 67-col. 9, line 4). Since the referenced formulation achieves the same desired results as applicant of sustained release, the

coating thickness claimed in the instant invention is not considered critical and is given no patentable weight. Although Morella does not disclose clarithromycin, claim 3 recites antibiotics as possible suitable pharmaceuticals to be used in the formulation. It would have been obvious to one skilled in the art at the time of the invention to coat the formulation of Blank according to the coating amount and thickness of Morella with the reasonable expectation of obtaining a pharmaceutical composition which has good taste-masking properties and the desired sustained release.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blank in view of Yajima et al. (US 5707646). Blank teaches all of the limitations of the claim as stated above. Blank does not teach the use of clarithromycin as the active ingredient. Yajima discloses a pharmaceutical composition made of a core containing an active drug densely coated with a functional polymer (col. 2, lines 12-14). In example 1 in column 4, clarithromycin is the active drug and EUDRAGIT E is the polymer used to coat the drug. It would have been obvious to one skilled in the art at the time of the invention to make a formulation as taught by Blank containing the clarithromycin of Yajima with the reasonable expectation of producing a pharmaceutical powder which masks the bitter taste of the drug.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks et al. In view of Lu et al. Sparks discloses all of the limitations of the claims as stated above. Sparks does not disclose erythromycin as an active ingredient. Sparks does disclose clarithromycin. Lu teaches that clarithromycin is a bitter tasting closely related derivative of erythromycin. It would

have been obvious to one of ordinary skill in the art at the time of the invention to substitute clarithromycin as taught by Lu et al. for erythromycin as taught by Sparks with the reasonable expectation of producing a taste-masked pharmaceutical with controlled release.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is (703) 308-4638. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234 or 1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Alysia Berman
Patent Examiner
May 18, 1999